

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

UNITED STATES OF AMERICA,)

ex. rel.)

ELIZABETH A. COOLEY)

Plaintiff,)

v.)

Civil Action No. 1:20-cv-04181-TWT

ERMI, LLC f/k/a ERMI, INC.;)

THOMAS P. BRANCH, M.D.;)

CHUTE 15, INC.;)

ARTHRORESEARCH, LLC;)

ROBODIAGNOSTICS, LLC; and)

END RANGE OF MOTION)

IMPROVEMENT, INC.)

Defendants.)

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS’
MOTION TO DISMISS FIRST AMENDED COMPLAINT**

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ERMI, LLC f/k/a ERMI, Inc. (“ERMI”); Thomas P. Branch, M.D. (“Dr. Branch”); Chute 15, Inc.; Arthroresearch, LLC; Robodiagnostics, LLC; and End Range Of Motion Improvement, Inc. move to dismiss Relator Elizabeth A. Cooley’s (“Relator” or “Cooley”) First Amended Complaint (the “FAC”) (Doc. 28) for failure to state a claim and to plead necessary elements of her False Claims Act (“FCA”) claims with particularity pursuant to Fed. R. Civ. P. 8(a), 12(b)(6), and 9(b).

Defendants moved to dismiss the original 168-paragraph Complaint because, among other things, it was a textbook shotgun pleading, in violation of this Circuit’s basic pleadings standards, and failed to satisfy this Circuit’s particularity standards under Rule 9(b) applicable to FCA claims. Rather than cure these deficiencies, Relator has now amended her pleadings by adding *another 200+ paragraphs* consisting of largely repetitive, formulaic legal-elements language with little factual detail. Critically, nowhere in the FAC’s meandering 370 shotgun-style paragraphs does Cooley ever allege any particular claim that was submitted to a government payor—much less a fraudulent one—and even the various schemes alleged lack any factual detail that can adequately apprise Defendants of the claims against them. The FAC is infected with numerous other pleading failures as well. Accordingly, the FAC should be dismissed, and this time with prejudice.

BACKGROUND AND SYNOPSIS OF FACTS ALLEGED

A. Procedural History

Cooley filed her Complaint on October 9, 2020, alleging violations of the FCA. (Doc. 1). On July 12, 2021, the United States provided notice that it was not intervening. (Doc. 8). After the Complaint was unsealed, Defendants moved to dismiss because: (1) the Complaint was an impermissible shotgun pleading, (2) the allegations failed to satisfy Rule 9(b), and (3) the FCA claims as pled suffered from specific other pleading deficiencies. (Doc. 24-1 at 7-25).¹ Cooley then filed her FAC. (Doc. 28). As explained below, the FAC fails to cure the above pleading defects and injects additional defects, now warranting dismissal with prejudice.

B. Summary of Allegations²

Relator Cooley, a registered nurse with a law degree, served as Chief Compliance Officer (“CCO”) for Defendant ERMI from November 2018 to October 2019. (Doc. 28 ¶ 2). ERMI manufactures and leases several types of durable medical equipment (“DME”), which assist orthopedic patients regain range of

¹ Pincites for docket filings refer to the ECF page number specifically.

² On a motion to dismiss for failure to state a claim under Rule 12(b)(6), this Court accepts the truth of facts alleged in the complaint. *United Techs. Corp. v. Mazer*, 556 F.3d 1260, 1269 (11th Cir. 2009). The facts recited herein are those alleged in the FAC. Defendants do not admit that any of the facts alleged in the Complaint are true.

motion in their joints. (*Id.* ¶¶ 1, 43-49). ERMI provides DME to patients covered by various federal health care benefit programs, including those administered by the Centers for Medicare & Medicaid Services (“CMS”) (i.e. Medicare), the U.S. Department of Labor’s Office of Workers’ Compensation Programs (“OWCP”), and the U.S. Department of Veterans’ Affairs (the “VA”). (*Id.* ¶¶ 11, 52, 70-82). Defendant Dr. Branch is a Board Certified orthopedic surgeon who founded ERMI and acts as its Chief Executive Officer and majority shareholder. (*Id.* ¶¶ 37, 39, 42).

Cooley alleges that Defendants violated the FCA by engaging in what the FAC characterizes as five different “schemes” to defraud these government payors in connection with ERMI’s leasing its DME to patients, resulting in the submission of false claims for reimbursement. (*See id.* ¶¶ 1, 4-26). The alleged schemes include:

- (1) billing the government for leasing ERMI devices to patients for 16 weeks despite internal company research suggesting that use of its devices may not be medically necessary beyond 10 weeks, (*id.* ¶¶ 4-8);
- (2) charging the VA and OWCP more than Medicare for the lease of certain devices and failing to disclose the price differential, (*id.* ¶¶ 9-16);
- (3) billing for ERMI devices leased in Florida without having proper state licensure, (*id.* ¶¶ 17-21);
- (4) billing for claims generated from illegal remuneration arrangements with physicians, in violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b, (*id.* ¶¶ 22-24); and
- (5) billing for claims generated from referrals in violation of the Stark Law, 42 U.S.C. § 1395nn, (*id.* ¶¶ 25-26).

Based on the above, the FAC asserts six counts alleging violations of 31 U.S.C. § 3729(a)(1)(A) & (B) (the FCA’s presentment and make-or-use provisions). (*Id.* ¶¶ 109-346). The FAC also asserts a count for conspiracy to violate the FCA, in violation of 31 U.S.C. § 3729(a)(1)(C), (*id.* ¶¶ 347-353), and a count for retaliation against Cooley, presumably in violation of 31 U.S.C. § 3730(h), (*id.* ¶¶ 354-369).

Absent from the FAC, however, is any particularized detail about a single claim that was submitted to a federal payor.

ARGUMENT AND CITATION OF AUTHORITY

On a motion to dismiss for failure to state a claim, this Court accepts the truth of the facts alleged in the complaint, *see United Techs. Corp. v. Mazer*, 556 F.3d 1260, 1269 (11th Cir. 2009), but does not accord such deference to speculations, opinions, or legal conclusions, *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To survive a motion to dismiss, Cooley must “provide the grounds for [her] entitlement to relief,” which “requires more than labels and conclusions, and a formulaic recitation of a cause of action’s elements will not do.” *Twombly*, 550 U.S. at 545 (cleaned up). The claims must be more than “conceivable”: they must allege “enough facts to state a claim to relief that is plausible on its face.” *Id.* at 570. It must set forth “enough factual matter (taken as true) to suggest [each] required element” of a claim. *Watts v. Fla. Int’l Univ.*, 495 F.3d 1289, 1295 (11th Cir. 2007).

In addition to satisfying Rule 12(b)(6)'s plausibility requirement, "[a] complaint under the FCA must meet the heightened pleading standard of Rule 9(b)." *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009). Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To state an FCA claim with particularity, "the complaint must allege facts as to time, place, and substance of the defendant's alleged fraud, and the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005). Because "[l]iability under the [FCA] arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or failure to maintain proper internal policies," this Circuit has held that "submission" of an actual fraudulent claim "must be pleaded with particularity and not inferred from the circumstances." *Id.* at 1012-13.

A. The FAC is a shotgun pleading.

The FAC is an impermissible shotgun pleading. *See Paylor v. Hartford Fire Ins. Co.*, 748 F.3d 1117, 1126 (11th Cir. 2014) (directing that a "defendant served with a shotgun complaint should move" for dismissal under Rule 12(b)(6)). "Shotgun pleadings violate Rule 8, which requires a short and plain statement of the claim showing that the pleader is entitled to relief, by failing to one degree or another

to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests.” *Vibe Micro, Inc. v. Shabanets*, 878 F.3d 1291, 1294-95 (11th Cir. 2018) (cleaned up). “Courts in the Eleventh Circuit have little tolerance for shotgun pleadings,” and dismiss them accordingly. *Id.* at 1295.

1. The FAC impermissibly bundles claims.

The original Complaint failed to “separate each cause of action or claim for relief into a different count.” *Barmapov v. Amuial*, 986 F.3d 1321, 1325 (11th Cir. 2021); (*see* Doc. 24-1 at 10-11). Cooley did exactly what relators have been ordered *not* to do: she “lump[ed] [her] Make-or-Use Claim in with [her] Presentment Claim in” the same count. *United States v. Fulton Cty.*, No. 1:14-CV-4071-WSD, 2016 WL 4158392, at *11 n.17 (N.D. Ga. Aug. 5, 2016) (noting such “bad pleading practice”).

The FAC makes the problem exponentially worse. It still bundles presentment and make-or-use claims in Counts I through VI (without providing any specific factual allegations in support of the make-or-use claims). (*See* Doc. 28 ¶¶ 123, 164). But worse, embedded within these counts is a whole array of different claims and theories. Each parrots presentment of false claims, making or using false records or statements, assorted false certifications tracking the language of different statutory and regulatory provisions, and various concealments or nondisclosures, and these formulations are repeated from count to count with little differentiation. (*Id.* ¶¶ 119,

123-127, 163-168, 196, 202, 206, 213-220, 252, 276, 278-284, 305, 308, 316-325, 339-343).³ Relator’s apparent strategy is that by blending the same legal formulations together in each count, somewhere in the allegation soup there might be a stated claim that can proceed to discovery. Courts do not tolerate that approach and dismiss accordingly. *See, e.g., U.S. ex rel. Musachia v. Pernix Therapeutics, LLC*, No. 2:18-CV-01445-RDP, 2021 WL 2826429, at *5 (N.D. Ala. July 7, 2021) (“Plaintiff’s attempt to assert various theories of liability in the same count fails to provide a clear and plain statement required under Rule 8(a), let alone doing so with particularly under Rule 9(b).”); *United States v. Norman*, No. 8:15-CV-1506-T-23AEP, 2018 WL 264253, at *1 n.4 (M.D. Fla. Jan. 2, 2018) (accord).

2. The FAC impermissibly bundles defendants.

The original Complaint also impermissibly bundled multiple Defendants together in the allegations rather than provide “specific allegations with respect to each defendant.” *W. Coast Roofing & Waterproofing, Inc. v. Johns Manville, Inc.*, 287 F. App’x 81, 86 (11th Cir. 2008); *see also Norman*, 2018 WL 264253, at *1. Likewise, the FAC still bundles Defendants ERMI and Dr. Branch together as

³ Cooley also bundles claims with no differentiation based on the government payor at issue. For example, Cooley does not allege that ERMI made any kind of certification to the VA whatsoever, let alone a false one. Thus, all false certification claims in Counts I-VI based on the VA payor channel must be dismissed.

though they are one in the same, often simply referring to “ERMI and Branch” without stating which Defendant did what. (Doc. 28, *passim*). Such lumping together of defendants warrants dismissal. *See, e.g., Norman*, 2018 WL 264253, at *1 (dismissing pursuant to Rule 9(b) for lumping defendants).

Furthermore, in the FAC (as before), Chute 15, Inc.; Arthroresearch, LLC; Robodiagnostics, LLC; and End Range Of Motion Improvement, Inc. (the “Non-ERMI Entities”) are never alleged to have engaged in any conduct at all. Conduct by ERMI and Dr. Branch cannot simply be imputed to these other Defendants. *See U.S. ex rel. Silva v. VICI Mktg., LLC*, 361 F. Supp. 3d 1245, 1255-56 (M.D. Fla. 2019) (dismissing corporate defendant where complaint failed to plead fraud with particularity as to that defendant and rejecting imputation of individual defendant’s conduct to corporate defendant).

Nor are the FAC’s conclusory veil-piercing or “alter ego” allegations reason for setting aside Rule 9(b)’s requirements. The FAC simply parrots various “alter ego” elements, but alleges no *facts* in support of such an alter ego theory against the Non-ERMI Entities. (*See* Doc. 28 ¶¶ 56-59).⁴ “The burden for establishing” an alter

⁴ Even if the lone conclusory veil-piercing allegation in ¶ 59 was somehow sufficient to support piecing *ERMI’s* corporate veil to reach Dr. Branch, there is no warrant for retaining the *Non-ERMI* Entities as Defendants. This action entirely concerns ERMI’s billing activities, not any alleged conduct attributable to these other entities.

ego or veil-piercing theory, however, “is quite high and such findings are considered ‘rare.’” *U.S. ex rel. Lewis v. Cmty. Health Sys., Inc.*, No. 18-20394-CIV, 2020 WL 3103994, at *20 (S.D. Fla. June 11, 2020). Courts routinely dismiss claims under Rule 9(b) that fail to contain “specific allegations with respect to each defendant,” notwithstanding inclusion of perfunctory alter ego allegations. *W. Coast Roofing & Waterproofing*, 287 F. App’x at 86; *see, e.g., United States v. Genesis Global Healthcare*, No. 4:18-CV-128, 2021 WL 4268279, at *10 (S.D. Ga. Sept. 20, 2021) (relators “failed to allege facts sufficient to show plausible liability under the FCA based on an alter ego theory of liability” and failed to satisfy Rule 9(b) as to those defendants); *Lewis*, 2020 WL 3103994, at *20 (accord); *McGee v. S-Bay Dev., LLC*, No. 8:11-CV-1091-T-27TGW, 2012 WL 760797, at *9 (M.D. Fla. Mar. 8, 2012) (veil-piercing allegations were “simply legal conclusions, which [were] not supported by any facts”). The Court should likewise do so here.

B. The FAC does not satisfy Rule 9(b).

The FAC must also be dismissed because the allegations fall woefully short of this Circuit’s long-established particularity standards under Rule 9(b), as stated in *United States ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002). In *Clausen*, a relator alleged that a company engaged in a multi-faceted, decade-long campaign to defraud the Government through six

fraudulent schemes resulting in the submission of false claims for reimbursement. 290 F.3d at 1302-03. This Court dismissed because the relator had not “identified a single fraudulent claim by date filed, amount or claim number that was actually submitted to the government.” No. 1:97CV2200TWT, 2001 WL 1867721, at *1 (N.D. Ga. May 16, 2001) (Thrash, J.). This Court explained that the relator had “merely described the allegedly illegal contracts and arrangements without identifying any person, place or time when an actual false claim or other illegal activity occurred” and thus at most alleged “a general scheme or methodology by which defendants could have violated the [FCA].” *Id.* In concluding that such allegations were “simply insufficient under Rule 9(b),” this Court reasoned that the “particularity requirement of Rule 9 [would be] a nullity if Plaintiff gets a ticket to the discovery process without identifying a single false claim by amount.” *Id.*

This Circuit agreed and affirmed. 290 F.3d at 1311, 1315. The court explained that, under Rule 9(b), not only must a relator plead a fraudulent scheme with particularity—i.e. pleading “facts as to time, place, and substance of the defendant’s alleged fraud,” including “the details of the defendants’ allegedly fraudulent acts, when they occurred, and who engaged in them”—but must also plead with particularity the actual submission of false claims. *Id.* at 1310-11. That is because “submission of a claim” is the “*sine qua non* of a[n FCA] violation.” *Id.* at 1311.

Hence, an FCA relator may not merely “describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.” *Id.* Instead, the complaint must contain “some indicia of reliability ... to support the allegation of *an actual false claim* for payment being made to the Government.” *Id.* The Eleventh Circuit has repeatedly reaffirmed this standard in both published and unpublished decisions.⁵

Cooley asserts presentment, “make-or-use,” and conspiracy FCA claims. (Doc. 28 ¶¶ 109-353). Rule 9(b)’s particularity requirements apply to each of these. *Hopper*, 588 F.3d at 1328 (holding that Rule 9(b) applies to both presentment and make-or-use FCA claims); *U.S. ex rel. Chase v. HPC Healthcare, Inc.*, 723 F. App’x 783, 791 (11th Cir. 2018) (same for FCA conspiracy claims).

As before, the FAC contains no particularized allegations of any actual false claims that were submitted to a government payor. Cooley describes various kinds of conduct that she contends necessarily resulted in the submission of fraudulent claims, but she does not allege any specific billing information for any particular

⁵ See, e.g., *Corsello*, 428 F.3d at 1012 (affirming dismissal for failure to satisfy Rule 9(b)); *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006) (same); *Hopper*, 588 F.3d at 1325, 1328 (same); *U.S. ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302-03 (11th Cir. 2010) (same).

claims she contends were fraudulently submitted. *See Chase*, 723 F. App'x at 789 (explaining that “indicia of reliability” requirement that submission of an actual false claim be alleged with particularity can be satisfied by “alleging the details of false claims by providing specific billing information—such as dates, times, and amounts of actual false claims or copies of bills”); *accord U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 704 (11th Cir. 2014).

For example, the FAC alleges that ERMI submitted claims “to the United States” for Florida patients during certain time periods when ERMI did not have a valid state license. (Doc. 28 ¶¶ 196, 202, 273,274). But it does not identify a single actual claim falling into that category with particularity, only alleging, in conclusory fashion, that “every single invoice” submitted by ERMI during certain time periods must have been a false claim. (*Id.*, ¶¶ 215, 278). Likewise, the FAC alleges that certain claims were the product of unlawful kickback arrangements with *unnamed* prescribing physicians. (*Id.*, ¶ 294). But again, the FAC does not identify a single actual claim falling into that category with particularity, only alleging that ERMI must have submitted “numerous claims” tainted by a kickback. (*Id.*, ¶ 319). Finally, the FAC claims that ERMI provided DME to patients referred to it in violation of the Stark law. (*Id.*, ¶¶ 335-336). The FAC does not identify any actual patients or claims submitted in this category, only that ERMI “routinely submitted” Stark-

tainted claims to federal payors. (*Id.*, ¶ 337).⁶ But to satisfy Rule 9(b), a relator may not “rely on mathematical probability to conclude that the [defendant] surely must have submitted a false claim at some point. Again, a relator must allege an ‘actual false claim for payment’ that was presented to the government. Speculation that false claims ‘must have been submitted’ is insufficient.” *Carrell v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1275 (11th Cir. 2018) (cleaned up).

Some of Cooley’s FCA allegations are premised on alleged false certifications of compliance that purportedly tainted whole categories of submitted claims. That approach also does not ameliorate Rule 9(b)’s particularity requirements. Failure to identify any particular submitted claims that resulted from these alleged false certifications dooms those allegations as well. *See, e.g., Est. of Helmy v. Bethany Hospice & Palliative Care of Coastal Ga., LLC*, 853 F. App’x 496, 501 (11th Cir. 2021) (no indicia of reliability for relators’ AKS-based FCA claims where they “failed to allege any specifics about actual claims submitted to the government”); *Musachia*, 2021 WL 2826429, at *8 (same where allegations did not contain “any information regarding claims, billing information, dates of submission, bills submitted, amounts charged to the Government, or any amount received from the

⁶ The schemes at issue in Counts I-II likewise suffer from the same defect.

Government”); *see also, e.g., U.S. ex rel. D’Anna v. Lee Mem’l Health Sys.*, No. 2:14-CV-437-FTM-38CM, 2019 WL 1061113, at *4 (M.D. Fla. Mar. 6, 2019).

The FAC also fails to provide “details of the defendants’ allegedly fraudulent acts, when they occurred, and who engaged in them”—i.e. particularized details about the alleged schemes themselves. *Clausen*, 290 F.3d at 1310. That does not suffice. *See, e.g., Chase*, 723 F. App’x at 790 (failure to allege AKS scheme with particularity where relator failed to identify any individuals who made improper referrals, any individual improperly referred patients, who provided the bribes, or when those exchanges took place); *United States v. Choudhry*, No. 8:13-CV-2603-T-27AEP, 2017 WL 2604930, at *5 (M.D. Fla. June 14, 2017) (same).

Of course, Cooley may tout her “insider status” as the former CCO of ERMI. (*See* Doc. 28 ¶ 2). While this Circuit has sometimes been “more tolerant toward complaints that leave out some particularities of the submissions of a false claim if the complaint also alleges personal knowledge or participation in the fraudulent conduct,” *U.S. ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1230 (11th Cir. 2012), that route cannot save the FAC given the utter lack of detail regarding Cooley’s knowledge of ERMI’s billing practices or procedures or any direct participation on her part in the claims submission process. Indeed, all Cooley mentions about her involvement with the alleged schemes is attending a few

meetings, having a few general conversations, receiving a random email, and signing a state license application. (Doc. 28 ¶¶ 118, 159-160, 254-259, 299, 304, 360-61).⁷

Courts in this Circuit have required far more than that of insiders hoping to unlock the doors to discovery without providing the kind of particularized billing information about specific fraudulent claims that Eleventh Circuit caselaw ordinarily requires. *E.g.*, *Est. of Helmly*, 853 F. App'x at 501-02 (rejecting relators' insider status allegations because despite having attended a few meetings and claiming to have "direct knowledge of the defendants' billing and patient records," they were unable to provide any specific details regarding defendants' submission of claims, "did not claim to have observed the submission of an actual false claim," and did not "personally participate in the submission of false claims"); *Carrel*, 898 F.3d at 1278 (rejecting indicia of reliability argument based on relator's alleged "personal

⁷ Cooley has already acknowledged that she lacks personal knowledge of any fraudulent submission of claims regarding the alleged Stark Law scheme (i.e. Count VI). In her original Complaint, those allegations were based "[u]pon information and belief." (Doc. 1 ¶ 129). Allegations based on information and belief do not satisfy Rule 9(b)'s particularity standard. *Corsello*, 428 F.3d at 1013-14 (allegations based "on information and belief" "lacked the 'indicia of reliability' required by *Clausen* because they failed to provide an underlying basis for [relator's] assertions"). After Defendants pointed this out in their first motion to dismiss, (Doc. 24-1 at 18 n.7), Cooley conveniently removed all "upon information and belief" verbiage from the FAC, including from the allegations regarding the alleged Stark Law scheme. (See Doc. 28 ¶¶ 337, 339-343). The bell has already been rung though.

knowledge or participation’ in the alleged fraud” where “relators failed to explain how their access to possibly relevant information translated to knowledge of actual tainted claims presented to the government”).

In sum, because the FAC contains no indicia of reliability regarding the actual submission of fraudulent claims to the government, all of Cooley’s FCA claims under Counts I through VII must be dismissed for failure to satisfy Rule 9(b).⁸

C. The FAC fails to plead materiality with particularity.

Cooley’s FCA claims must also be dismissed for failure to plead materiality with particularity. The FAC formulaically recites that certain false records or statements were “material to claims for payment or approval,” or that certain other actions, omissions, or statements “were material,” (Doc. 28 ¶¶ 123, 153, 164, 175), but not once does the FAC ever allege any *facts* establishing materiality.

⁸ Cooley’s pricing concealment claim (Count II) is particularly threadbare. That theory appears to be modeled after a similar theory advanced in *U.S. ex rel. Morsell v. Symantec Corp.*, 130 F. Supp. 3d 106, 119-21 (D.D.C. 2015) (discussing FCA claim premised on company’s failure to disclose more favorable pricing pursuant to a Price Reduction Clause in its GSA contract). (See Doc. 28 ¶¶ 9-14, 134-178). In *Morsell*, the plaintiff satisfied Rule 9(b) by providing detailed allegations of the contractual terms at issue, allowing the court to assess the complaint’s nondisclosure allegations against the contract’s terms. See *Morsell*, 130 F. Supp. 3d at 110-14. The FAC, by contrast, fails to discuss any terms in ERMI’s GSA contracts, requiring the conclusory allegation that ERMI breached its contracts to be taken simply at face value. That is woefully insufficient under Rule 9(b).

That especially dooms Cooley’s false certification FCA claims. (*See* Doc. 28, *passim* (alleging numerous false certifications, representations, and omissions)). While misrepresentations about regulatory compliance can be actionable under a false certification theory, any such misrepresentation must “be material to the government’s payment decision.” *Universal Health Servs., Inc. v. U.S. ex. rel. Escobar*, 136 S. Ct. 1989, 2002 (2016).⁹ “The materiality requirement is both ‘rigorous’ and ‘demanding,’ and must be pled with particularity.” *Fulton Cty.*, 2016 WL 4158392, at *8 (quoting *Escobar*, 136 S. Ct. at 2004 n.6). “[S]tatutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment.” *Escobar*, 136 S. Ct. at 2001. “Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant’s noncompliance.” *Id.* at 2003. “Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.” *Id.*

Under that standard, the FAC’s allegations clearly fail. Cooley just assumes that the government payors at issue would consider the various alleged instances of statutory or regulatory noncompliance to be material to their payment decision, but

⁹ Counts III-VI’s allegations that various representations or omissions were material to *AHCA*, a state agency, is irrelevant. Only materiality with respect to a *federal* payor matters. *See Escobar*, 136 S. Ct. at 2002.

does not allege any facts in support. That does not satisfy Rule 9(b)’s “rigorous” and “demanding” particularity requirement. *Norman*, 2018 WL 264253, at *2 (dismissing false certification claim for failure to allege materiality where relator failed to allege that United States routinely refused to reimburse providers due to noncompliance); *U.S. ex rel. Payton v. Pediatric Servs. of Am., Inc.*, No. CV416-102, 2017 WL 3910434, at *10 (S.D. Ga. Sept. 6, 2017) (same explaining, “[Relator] must do something more than simply state that compliance is material”).

Moreover, only violations of conditions of **payment** can serve as a predicate under a false certification theory, not merely violations of conditions of **participation** in the government program. *See United States v. Health Mgmt. Assocs., Inc.*, No. 4:10-CV-10013-KMM, 2013 WL 12077815, at *4 n.2 (S.D. Fla. Mar. 1, 2013) (explaining difference between conditions of payment versus participation for purposes of FCA liability (citing *Clausen*, 290 F.3d at 1311)). Cooley fails to allege that any of the various instances of noncompliance in the FAC were conditions of payment rather than mere conditions of participation.¹⁰ In sum, Cooley’s failure to allege materiality with particularity warrants dismissal of her FCA claims.

¹⁰ Most of the regulatory provisions Cooley cites—which her false certification allegations are based on—are plainly conditions of program participation, not conditions of payment. (*See, e.g.*, Doc. 28 at 23-24 (citing 42 C.F.R. § 424.57(c) (providing standards DME supplier applicant “must meet and ... certify in its

D. The medical necessity count fails to adequately plead falsity.

Cooley’s medical necessity claim (Count I) also warrants dismissal for failure to adequately plead falsity. Her theory is that ERMI fraudulently bills government payors for 16 weeks of patient usage for certain of its devices despite unidentified “internal research” and “internal documents” suggesting that these devices may not be medically necessary after 10 weeks. (Doc. 28 ¶¶ 112-120).

But Cooley’s allegations completely overlook that questions of medical necessity turn on a *physician’s* medical judgment, not that of a provider whose services are authorized by a physician. In *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), the Eleventh Circuit rejected that medical necessity for a healthcare service, and hence objective falsity for purposes of the FCA, can be

application for billing privileges”)); *compare* 42 C.F.R. § 424.57(b) (providing conditions of payment)). For example, the crux of Counts III and IV is ERMI’s alleged failure to comply with state licensure and regulatory requirements in Florida. But under Medicare’s regulations, that merely implicates a condition of program participation under 42 C.F.R. § 424.57(c), not a condition of payment under 42 C.F.R. § 424.57(b). The FAC’s failure to allege materiality with respect to ERMI’s alleged licensure lapses thus warrants dismissal of those claims for that reason alone. *See U.S. ex rel. Taylor v. Boyko*, No. CV2:17-04213, 2019 WL 2423283, at *5 (S.D. W. Va. June 7, 2019) (dismissing FCA claim regarding licensure lapse for failure to allege materiality; complaint relied solely upon alleged regulatory violations regarding licensure lapse, without alleging additional facts showing materiality of licensure lapse to CMS payment decision).

assessed independent of the authorizing physician's medical judgment, holding instead that an FCA plaintiff seeking to establish a false certification theory based on lack of medical necessity "must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment." *Id.* at 1296-97; *see also id.* at 1295 (noting CMS commentary signaling that "well-founded clinical judgments should be granted deference").

Like the regulations at issue in *AseraCare*, *see id.* at 1292-93, the relevant regulations here leave it to a physician's judgment whether a patient needs certain DME, not the DME supplier. *See* 42 C.F.R. § 410.38(c)(4), (d)(1) (requiring as condition of payment a "written order/prescription ... from a treating practitioner that documents the need for a beneficiary to be provided" DME)¹¹; *see also* 20 C.F.R. § 10.310(a) (OWCP authorizes beneficiaries "to receive all medical services, appliances or supplies which a qualified physician prescribes or recommends" for work-related injury"). Cooley's allegations rely on vague references to ERMI's "internal research" and "documents" to challenge the medical necessity of patients' use of ERMI DME, without reference to any physician's clinical judgment.

¹¹ By contrast, the DME supplier simply "maintain[s] the written order/prescription and the supporting documentation provided by the treating practitioner" and makes them available upon request. 42 C.F.R. § 410.38(d)(3).

Furthermore, a court applying *AseraCare* recently dismissed FCA claims based solely on a single study that a relator claimed demonstrated a lack of medical necessity for certain medical services. *United States v. DaVita Inc.*, No. 8:18-cv-01250-JLS-DFM, 2020 WL 3064771, at *7-8, 10 (C.D. Cal. Apr. 10, 2020). Because relator’s allegations merely reflected his own “subjective difference of opinion with other physicians as to the medical necessity of certain treatments” and failed to account for the fact that “physicians applying their clinical judgment about a patient” could disagree, relator failed to plead the falsity element of his FCA claim. *Id.* at *8. Here, Cooley doesn’t furnish, or even identify the ERMI “internal research” on which her allegations are based. Her threadbare allegations warrant dismissal.

E. The Florida licensure claims are barred by public disclosure.

Counts III-IV are barred by the FCA’s public-disclosure bar. 31 U.S.C. § 3730(e)(4)(A). That statutory provision requires courts to dismiss an FCA claim “if substantially the same allegations were publicly disclosed prior to the initiation of the qui tam action.” *U.S. ex rel. Zafirov v. Fla. Med. Assocs.*, No. 8:19-CV-1236-KKM-SPF, 2021 WL 4443119, at *6 (M.D. Fla. Sept. 28, 2021) (dismissing FCA claim based upon public disclosure of scheme in prior litigation).

ERMI’s licensure lapses in Florida were the subject of multiple legal actions that *Relator’s counsel filed against ERMI* in Fulton County, Georgia and in Federal

Court in the Southern District of Florida *well before* Cooley’s original Complaint.¹² Cooley’s licensure allegations are “substantially the same” as the “allegations or transactions contained in [existing] public disclosures.” *Payton*, 2017 WL 3910434, at *5; *see id.* at *4-8 (discussing and applying Circuit’s public disclosure bar analysis). Additionally, given that the core licensure allegation was made before Cooley filed her Complaint, she is not an “original source” because she does not have “knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions.” *Id.*; *see also U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 210 (1st Cir. 2016) (affirming public-disclosure bar dismissal because “a complaint that targets a scheme previously revealed through public disclosures is barred even if it offers greater detail about the underlying conduct”). Thus, Counts III and IV warrant dismissal for this additional reason.

¹² This Court may take judicial notice of court records to decide whether the public-disclosure bar applies. *Zafirov*, 2021 WL 4443119, at *4 n.5; *Cordner v. Specialized Loan Servicing, LLC*, No. 15-2090, 2016 WL 3675557, at *4 (N.D. Ga. June 7, 2016), *report and recommendation adopted*, 2016 WL 3634722 (N.D. Ga. July 7, 2016) (taking judicial notice of court records). Accordingly, attached hereto as Exhibit A is a true and correct copy of the Complaint filed on August 28, 2019, in *Team Post Op, Inc. v. Thomas P. Branch, MD et al.*, No. 2019CV325917 (Fulton Super. Ct. 2019). Attached hereto as Exhibit B is a true and correct copy of the Complaint filed on January 24, 2020, in *In Re: ERMI LLC (‘289) Patent Litigation*, No. 0:19-MD-02914-RKA (S.D. Fla. 2019). To assess the similarity to Cooley’s licensure claims, ERMI directs the Court to Exhibit A, ¶¶ 1, 20-25, and Exhibit B, ¶¶ 104-122.

F. The conspiracy claim fails for lack of particularity.

The FAC fails to allege any particularized facts in support of Cooley’s conspiracy claim (Count VII). *See* 31 U.S.C. § 3729(a)(1)(C). To satisfy Rule 9(b), a relator alleging conspiracy must plead specific allegations of an “agreement” among defendants to obtain payment for a false claim and an overt act in furtherance of the agreement. *See Corsello*, 428 F.3d at 1014. Cooley’s allegations fail to do that, instead parroting rote legal-elements language with no factual detail supporting these elements. This warrants dismissal. *See, e.g., id.* (affirming dismissal of conspiracy claim where “bare legal conclusion” of conspiracy “was unsupported by specific allegations of any agreement or overt act”).

H. The FAC fails to state an FCA retaliation claim.

Finally, Cooley’s FCA retaliation claim (Count VIII) must be dismissed for failure to state a claim. To plead such a claim, “the Plaintiff must allege ‘unlawful discrimination,’ a ‘protected activity,’ and ‘a causal connection’ between the discrimination and protected activity.” *Cervalli v. Piedmont Healthcare, Inc.*, 551 F. Supp. 3d 1363, 1368 (N.D. Ga. 2021) (Thrash, J.). For the plaintiff to have engaged in a “protected activity,” there must have been “at least ‘a distinct possibility’ of litigation under the [FCA] at the time of the employee’s actions,” which means that the “employee’s actions, as alleged in the complaint, [were] sufficient to support a

reasonable conclusion that the employer could have feared being reported to the government for fraud or sued in a qui tam action by the employee.” *Id.*

There is a higher standard for alleging a “protected activity” when the plaintiff’s job duties consisted of overseeing compliance. For employees in those roles, merely complaining about compliance failures does not put the employer on notice that the plaintiff may file an FCA action. *United States v. KForce Gov’t Sols., Inc.*, No. 8:13-CV-1517-T-36TBM, 2014 WL 5823460, at *10 (M.D. Fla. Nov. 10, 2014) (“employees whose complaints fall within the scope of their job duties must provide their employers with clear notice of their intent to pursue an FCA action in order to satisfy the second element of a retaliation action under the statute”); *Brunson v. Narrows Health & Wellness LLC*, No. 2:06-CV-1148-AR, 2008 WL 11422063, at *5 (N.D. Ala. Mar. 31, 2008) (discussing “higher burden” for such plaintiffs). Courts in this Circuit have dismissed FCA retaliation claims premised merely on allegations that a compliance professional was “just doing his job,” *KForce Gov’t Sols.*, 2014 WL 5823460, at *10-11, or simply “attempting to make her employers comply with the rules” rather than doing something that might have “reasonably put her employers on notice that she was contemplating filing a qui tam action or seeking government intervention,” *Brunson*, 2008 WL 11422063, at *7.

All Cooley alleges is that ERMI or Dr. Branch “blocked” her efforts to ensure proper compliance by ERMI, or that Defendants harassed and ultimately terminated Cooley because of “her efforts to bring ERMI into compliance.” (Doc. 28 ¶¶ 356, 365, 367; *see generally id.* ¶¶ 355-367). But there is no allegation that Cooley ever said or did anything beyond her standard compliance functions to put ERMI on notice that she might pursue an FCA action for an alleged fraudulent billing scheme. Thus, Cooley has not alleged facts to support the “protected activity” element.

Additionally, the FAC fails to allege “‘a causal connection’ between the discrimination and protected activity.” *Cervalli*, 551 F. Supp. 3d at 1368. That requires showing that “the harm would not have occurred in the absence of” the “protected conduct.” *Id.* at 1370. Because the FAC fails to allege that Cooley engaged in any FCA protected activity, it necessarily fails to allege that the adverse employment actions she complains of stemmed from any such protected activity. For these reasons, the retaliation claim must be dismissed.

CONCLUSION

For all these reasons, the FAC should be dismissed fully with prejudice.

Respectfully submitted, this 4th day of October, 2021.

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CERTIFICATE OF COMPLIANCE

In compliance with N.D. Ga. R. 7.1D, I certify that the foregoing **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT** has been prepared in conformity with N.D. Ga. R. 5.1. This brief was prepared with Times New Roman (14 point) type, with a top margin of one and one-half (1 ½) inches and a left margin of one (1) inch. This brief is proportionately spaced and is no longer than twenty-five (25) pages.

/s/ Robert M. Brennan
Robert M. Brennan

CERTIFICATE OF SERVICE

I hereby certify that I have this day served a copy of the within and foregoing **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT** with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to the attorneys of record in this action.

This 4th day of October, 2021.

/s/ Robert M. Brennan
Robert M. Brennan